

REMARKS

Claims 1-19, 21, 23-76 and 82 were pending in the application. Claims 1, 19, 21, 23, 25, 28, 63 and 82 have been amended, claims 5, 15, 17, 18, 20, 27, 41-55, 69-81 and 83-102 have been cancelled without prejudice and claims 103-139 are new. Therefore, claims 1-4, 6-14, 16, 19, 21, 23-26, 28-40, 56-68, 82 and 103-139 are pending.

No new matter has been added. Support for the amendments to claims 1 and 82 can be found, for example, at least at page 23, line 36 of the specification as originally filed. Claim 28 has been amended to provide proper dependencies. Support for new claims 103-108 can be found, for example, at least in original claim 55 and at page 13, line 1 through page 14, line 1 and in Table 2 of the specification as originally filed. Support for new claims 109-139 can be found, for example, at least in original claims 53, 54 and 76 and at page 26, line 22 through page 29, line 7 and at page 29, line 35 through page 32, line 28 of the specification as originally filed.

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application. The cancellation of and/or amendments to the claims are not related to any issues of patentability.

Applicants gratefully acknowledge the Examiner's withdrawal of the rejections of the claims under 35 U.S.C. §102(b) and the withdrawal of the rejection of the claims under 35 U.S.C. §112, second paragraph, with regard to the terms "prodrug" and "steroidyl."

Rejection of Claims 1-10, 41-55, 69-76 and 82 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

The rejection of claims 1-10, 41-55, 69-76 and 82 has been maintained under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26, 32 and 51-81 of U.S. Patent No. 6,818,634.

Applicants submit that claims 1-26, 32 and 51-81 of U.S. Patent No. 6,818,634 are directed to compounds of formula (I) wherein R^7 is hydrogen, dialkylamino, heteroaryl-amino or R^9 is hydrogen or heteroaryl-amino. In the present application, claims 5, 41-55 and 69-76 have been cancelled and claims 1 and its dependent claims and claim 82, as amended, are directed to tetracycline compounds of the formula (I), wherein R^7 is hydrogen, dialkylamino, or $NR^{7c}C(=W')WR^{7a}$ and R^9 is hydrogen or $NR^{9c}C(=Z')ZR^{9a}$. Therefore, claims 1 and its dependent claims and claim 82 do not contain subject matter encompassed by claims 1-26, 32

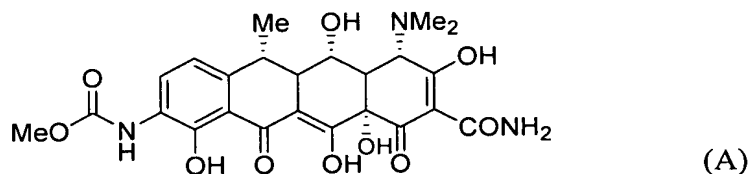
Rejection of Claims 1, 5, 9, 19, 27, 28, 63 and 82 Under 35 U.S.C. §112, second paragraph

With respect to the term “derivative,” the Examiner asserts that “[a]lthough examples of tetracycline derivatives are shown in table 1, derivatives is still not specifically defined” and that “exemplification is not an explicit definition.” Applicants respectfully traverse. However, to expedite prosecution, Applicants have cancelled claim 5 which renders this rejection moot.

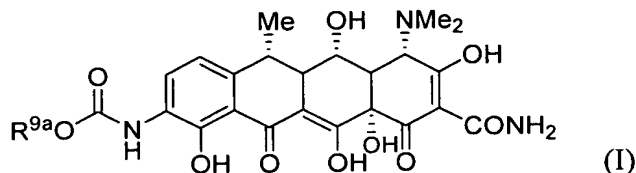
With respect to the term “multicyclic,” the Examiner asserts that “[a] skilled artisan is...led to believe that a multicyclic is a large functional group such as cholesterol, rather than naphthalene, for example” and that “[a]bsent a clear definition, ‘multicyclic’ is ambiguous.” Applicants respectfully traverse. However, to expedite prosecution, Applicants have amended claims 1, 19, 63 and 82, and have cancelled claim 27, which renders this rejection under 35 U.S.C. §112, second paragraph, moot.

Rejection of claims 1-5, 11-13, 16, 18, 19 and 82 Under 35 U.S.C. §103(a)

Claims 1-5, 11-13, 16, 18, 19 and 82 are rejected under 35 U.S.C. §103(a) as being unpatentable over Barden *et al.*, "Glycylcyclines 3. 9-Ameinodoxycyclinecarboxamides," *J. Med. Chem.*, 37(20):3205-11 (1994). Specifically, the Examiner asserts that Barden *et al.* disclose the compound and pharmaceutical compositions comprising the compound of the formula A



and that the present invention discloses compounds of formula (I)



in which R^{9a} is ethyl. The Examiner further asserts that “[t]he instant claimed compounds would have been obvious [over Barden *et al.*] because one skilled in the art would have been motivated

to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which would be useful in pharmaceutical compositions” and “[t]herefore, the instant claimed compounds would have been suggested to one skilled in the art.”

Applicants respectfully traverse this rejection. While Barden *et al.* discloses that simple amides, such as compounds of formula (A) “were highly active against tet-sensitive strains,” they were inactive against tet-resistant organisms. Further, Barden *et al.* states that “[p]rimary amides with larger alkyl chains...were significantly less active” and that limited activity of the tetracycline compounds disclosed by Barden *et al.* was not observed until a nitrogen atom was incorporated into the 9-position side chain (see, for example, last paragraph of the second column on page 3206). Accordingly, one skilled in the art would not have been motivated to prepare compounds of Applicants’ formula (I) in which R^{9a} is ethyl or other unsubstituted alkyl chain.

Notwithstanding the foregoing, claim 1 and its dependent claims and claim 82 have been amended to be directed to compounds of formula (I), wherein R⁹ is hydrogen or NR^{9c}C(=Z')ZR^{9a} and R^{9a} R^{9a} is substituted alkyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, arylsulfonyl, alkoxycarbonyl, arylcarbonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic, a steroid, absent, or a prodrug moiety. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Application No.: 10/786710
Examiner: A.B. Freistein

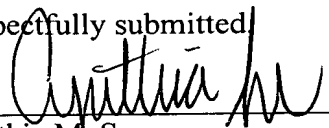
Docket No.: PAZ-025CPCN
Group Art Unit: 1626

SUMMARY

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. PAZ-025CPCN from which the undersigned is authorized to draw.

It is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expedition prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Dated: August 25, 2006

Respectfully submitted
By 
Cynthia M. Soroos
Registration No.: 53,623
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney/Agent For Applicant